

**Appl. No.** : 10/068,447  
**Filed** : February 6, 2002

### **REMARKS**

Claims 26-32 and 34-44 are pending in the present application. Claims 31 and 34-44 have been cancelled to clarify the scope of the instant application. Applicant reserves the right to pursue canceled Claims 31 and 34-44 in a divisional, continuation, or continuation-in-part application. New Claim 45 has been added. Accordingly, Claims 26-30, 32 and new Claim 45 are now pending. Support for new Claim 45 can be found in the specification and claims as originally filed, for example, at paragraphs [0042] and [0050]. Accordingly, no new matter has been added to the application.

In view of the remarks set forth below, Applicant respectfully requests reconsideration of the application and submits that the application is now in condition for allowance.

#### Rejections Under 35 U.S.C. § 102

The Examiner has rejected Claims 26-32 and 35-37 under 35 U.S.C. § 102(b), as allegedly being anticipated by Hellstrand *et al.*, WO 97/42968 (WO '968). Specifically, the Examiner asserts that WO '968 teaches a method for obtaining a composition containing histamine salts; the composition comprising a carrier and in transdermal formulation. The Examiner further asserts that the substance produced by the method described in WO '968 results in the release of higher endogenous histamine, the endogenous releasing compound is retinoic acid or IL-3 or allergens, and the composition formed is a gel.

The Examiner has also rejected Claims 26, 29 and 34 under 35 U.S.C. § 102(b), as allegedly being anticipated by Jack *et al.*, WO 95/23601 (WO '601). Specifically, the Examiner asserts that WO '601 teaches a method and composition for topical treatment of damaged tissue using histamine as an active ingredient. Additionally, the Examiner asserts that WO '601 teaches histamine phosphate in a medication for the topical treatment of sunburn as well as for other skin conditions.

In response to Applicant's previous response, the Examiner states that the biochemical effect of the composition in increasing endogenous histamine is the critical issue and unless a criticality is shown, a pharmaceutically acceptable carrier or a cosmetically acceptable carrier would be just as effective because it is a composition.

**Appl. No.** : 10/068,447  
**Filed** : February 6, 2002

To be anticipatory under 35 U.S.C. § 102, a reference must teach each and every element of the claimed invention. *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379 (Fed. Cir. 1986). “Invalidity for anticipation requires that all of the elements and limitations of the claim are found within a single prior art reference. . . . There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention.” *See Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565 (Fed. Cir. 1991) (emphasis added).

Applicant respectfully submits that neither reference anticipates the claims of the instant application. Applicant notes that Claims 31 and 35-37 have been cancelled by way of this amendment. Accordingly, the pending claims of the instant application relate to a method for making a cosmetic composition. “Cosmetic” is defined as “serving to beautify” or “used or done superficially to make something look better, more attractive, or more impressive.” Random House Unabridged Dictionary (2d ed. 1993). Thus, the claimed invention relates to compositions that not only serve to treat an underlying skin condition, but also to superficially modify the appearance of the skin while undergoing treatment. Accordingly, in some embodiments, the compositions include adornments such as color, fragrance, and texture.

WO ‘968 discloses pharmaceutical compositions comprising a compound selected from the group consisting of histamine, histamine dihydrochloride, histamine phosphate, histamine salts, histamine esters, H<sub>2</sub> receptor agonists, 5HT antagonists, serotonin, retinoic acid, retinoids, IL-3, ingestible allergens and a pharmaceutically acceptable carrier such as water, ethanol, polyols, liquid polyethylene glycols and oils. The compositions and methods disclosed in WO ‘968 concern the treatment of the malignancies or infectious diseases disclosed therein. Applicant notes that the Examiner alleges that WO ‘968 discloses a composition in the form of a gel (a shampoo), however, having completed a detailed review of the reference, Applicant submits that WO ‘968 is completely silent as to a composition in the form of a shampoo.

WO ‘601 describes a method and composition for topical treatment of damaged tissue using histamine phosphate as the active ingredient. The damaged tissue includes the diseases of herpes labialis, aphthous stomatitis, lesions, herpes genitalis, chicken pox, allergic conjunctivitis, giant papillary conjunctivitis, stomatitis secondary to chemotherapy, oral mucositis secondary to chemotherapy, thermal burn, sunburn, decubitus ulcers, and shingles.

**Appl. No.** : 10/068,447  
**Filed** : February 6, 2002

The claims of the instant application are directed to a method for making a cosmetic composition comprising an effective dose of a histamine or histamine-related compound that inhibits the production and release of ROMs in a cosmetically acceptable carrier. Thus, the compositions made according to the claimed methods not only treat skin disorders, but also function as cosmetic products, thus the compositions treat the disorder while superficially improving the appearance of the patient. WO '968 and WO '601 disclose only therapeutic compositions. Thus, neither of the cited references discloses a method for making compositions that simultaneously treat and improve the appearance of the patient, as neither reference discloses a method for making a cosmetic composition.

Skin disorders can have a significant impact on a patient's confidence about his or her appearance. Thus, the effects of skin disorders can be as much emotional as they are physical. Traditional therapeutic compositions focus on remedial agents that simply treat the disease while neglecting a patient's aesthetic concerns. Thus, traditional therapeutics do not resolve all of the issues that disorders of the skin present. While traditional therapeutics address the underlying disease state, the claimed invention provides a significant advancement in that it provides methods for making cosmetic compositions thereby addressing both the underlying disease state and the immediate appearance of the patient, thus promoting healthy mental and physical living. This difference between a traditional therapeutic composition and a cosmetic composition is substantial from a patient's perspective. While WO '968 discloses pharmaceutically acceptable carriers, such as polymers, gels, microspheres, and liposomes, and WO '601 discloses a water soluble vinyl polymer gel base, neither reference considers a carrier that will modify and improve the immediate appearance of the patient. Likewise, neither reference considers ingredients such as color, fragrance, and texture, or any other aesthetic feature considered in the methods of the claimed invention. Because anticipation requires that there be no difference between the claimed invention and the reference disclosures, Applicant respectfully submits that the cited references do not anticipate the claimed invention.

Because neither WO '968 nor WO '601 teaches every limitation of the claimed invention, pending Claims 26-30 and 32 are novel under 35 U.S.C. § 102(b). Accordingly, Applicant respectfully requests withdrawal of all rejections under this section and allowance of the pending application.

**Appl. No.** : 10/068,447  
**Filed** : February 6, 2002

Rejection Under 35 U.S.C. § 103

The Examiner rejected Claims 26-32, 34-42 and 44 under 35 U.S.C. § 103(a) as being unpatentable over WO '968 in view of WO '601 further in view of Bathurst *et al.*, U.S. Patent No. 6,004,579 (the '579 patent).

The Examiner applies WO '968 and WO '601 as discussed in the rejections under 35 U.S.C. § 102(b). The Examiner notes that neither patent discloses a method for making a composition wherein histamine phosphate is the active ingredient and is also formulated to contain fragrance and colorants. The Examiner asserts that the '579 patent discloses a method of making a topical composition for the treatment of dermatological compositions; said compositions formulated as liquids, creams, lotion, ointment, suntan lotion, sunscreen, etc. The Examiner asserts that one of ordinary skill in the art would be motivated to make a dermatologic composition for topical application as disclosed in the cited prior art reference and include cosmetically acceptable carriers and ingredients such as fragrances and colorants. The Examiner states that the motivation to combine the references lies in the reasonable expectation of success in achieving the beneficial effects of the composition in treating various dermatological conditions as disclosed in the '579 patent.

To establish a *prima facie* case of obviousness, three basic criteria must be met: first, there must be a suggestion or motivation to modify the reference to achieve the claimed invention; second, there must be a reasonable expectation of success derived from the cited reference in practicing the claimed invention; and third, the cited references must teach or suggest all the limitations of the claimed invention. M.P.E.P. § 2143. Applicant respectfully submits that the Examiner has failed to establish a *prima facie* case of obviousness and that the present rejection should be withdrawn.

The first criterion in establishing a *prima facie* case of obviousness is that there must be a suggestion or motivation to modify the reference or to combine reference teachings to achieve the claimed invention. "[I]t is necessary to ascertain whether or not the reference teachings would appear to be sufficient for one of ordinary skill in the relevant art having the reference before him to make the proposed substitution, combination, or other modification." *In re Linter*, 458 F.2d 1013, 1016 (CCPA 1972); M.P.E.P. § 2143.01. A comparison of the pending claims with the subject matter disclosed in the cited references shows that these references do not

**Appl. No.** : 10/068,447  
**Filed** : February 6, 2002

provide the necessary teachings to practice the claimed invention. Therefore, the cited references are insufficient to support an obviousness rejection.

Applicant notes that Claims 31, 34-42 and 44 have been cancelled by way of this amendment. Accordingly, the pending claims of the instant application relate to a method for making a cosmetic composition, wherein the composition comprises an effective dose of histamine or a histamine-related compound that inhibits the production and release of ROMs in a cosmetically acceptable carrier. Thus, in some embodiments, the compositions include adornments such as color, fragrance, and texture.

As discussed above, unlike traditional therapeutic agents that simply treat a disease, cosmetic compositions focus on the treatment of the disease while simultaneously addressing the patient's aesthetic concerns. Accordingly, cosmetic compositions include ingredients such as color, fragrance, and texture, or any other aesthetic features. This difference between a traditional therapeutic composition and a cosmetic composition is substantial from a patient's perspective when considering the aesthetics of disease treatment.

WO '968 is applied as in the rejection under 35 U.S.C. § 102 above. The compositions disclosed in WO '968 are described throughout the disclosure as combination treatments, however none of the disclosed combinations include a cosmetic carrier or the like. WO '601 is likewise applied as in the rejection under 35 U.S.C. § 102 above. The compositions disclosed in WO '601 are described throughout the disclosure as providing "an effective remedy," or "an improved medication and treatment," or the like. Both references lack any teaching or suggestion of a method for making a cosmetic composition which, in addition to treating the underlying condition, superficially improves the immediate appearance of the patient. Prior to the claimed invention, methods for making cosmetic compositions comprising a histamine or a histamine-related compound in a cosmetically acceptable carrier were not contemplated. The benefits of formulating the compositions comprising histamine or histamine-related compounds to take into account a patient's aesthetic concerns were unrecognized. Neither WO '968 nor WO '601 considered, much less addressed, a patient's aesthetic concerns, and thus neither provides a teaching or suggestion to provide the disclosed methods for making cosmetic compositions for topically delivering a compound that inhibits the production and release of enzymatically produced ROMs.

**Appl. No.** : 10/068,447  
**Filed** : February 6, 2002

Nevertheless, the Examiner asserts that claimed invention is obvious in view of the '579 patent, which teaches that the phospholipid-containing compositions disclosed therein can be formulated into various topically acceptable liquids, creams, lotions, gels, etc. The Examiner concludes that one of skill in the art would have been motivated to make a dermatologic composition for topical application as disclosed in the cited prior art reference and include cosmetically acceptable carriers and ingredients as fragrances and colorants. The Examiner asserts that the motivation to combine the references lies in the reasonable expectation of success in achieving the beneficial effects of the composition in treating various dermatological conditions as disclosed in the '579 patent. However, there is no teaching or suggestion in the '579 patent to use cosmetic carriers with compositions other than phospholipid-containing compositions, namely Elirex™. Thus, the necessary suggestion or motivation to combine the references is absent.

The second criterion of obviousness is that there must be a reasonable expectation of success derived from the cited reference in practicing the claimed invention. *In re Merck & Co., Inc.*, 800 F.2d 1091 (Fed. Cir 1986); M.P.E.P. § 2143.02. At least some degree of predictability is required with respect to a reasonable expectation of success. None of the cited references teaches the claims of the instant application nor do the cited references provide one of skill in the art with a reasonable expectation of success in practicing the claimed invention. In fact, WO '968 and WO '601 are completely silent as to the benefits of administering compounds in cosmetically acceptable carriers. Therefore, these references do not provide sufficient teachings to render the claimed invention obvious. Furthermore, there is no discussion in the '579 patent concerning providing compositions other than phospholipid compositions in a cosmetic carrier. Moreover, the '579 patent does not teach or suggest the cosmetic carriers recited in the claims of the instant application. In the absence of such teachings, one of skill in the art would have no reasonable expectation of success in making cosmetic compositions comprising histamine and histamine-related compounds based on the disclosure of the '579 patent. Given the lack of a reasonable expectation of success when practicing the claimed invention in view of the cited art, the second criterion for establishing a *prima facie* case of obviousness has not been met.

The third criterion is that the cited art must teach or suggest all the limitations of the claims. "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385 (CCPA 1970); M.P.E.P. § 2143.03. The

**Appl. No.** : **10/068,447**  
**Filed** : **February 6, 2002**

claims of the instant application relate to a compound selected from the group consisting of histamine, histamine dihydrochloride, histamine diphosphate, other histamine salts, esters, prodrugs, histamine-receptor agonists, serotonin, and 5HT agonists in a cosmetically acceptable carrier. As discussed above, WO '968 and WO '601 do not teach or suggest providing the disclosed compounds in cosmetically acceptable carriers. In addition, the '579 patent does not disclose the use of compounds other than the phospholipid-containing compounds, nor does it teach the specific cosmetic carriers claimed herein. Because the cited art does not teach or suggest all limitations of the claims, this criterion of obviousness has not been established.

In light of the foregoing, Applicant respectfully submits that pending Claims 26-30 and 32 are not obvious under 35 U.S.C. § 103 in view of WO '968, WO '601 and the '579 patent. Accordingly, Applicant hereby requests that this rejection be withdrawn.

#### **CONCLUSION**

For the foregoing reasons, it is respectfully submitted that the rejections set forth in the outstanding Office Action have been addressed and that the application is now in condition for allowance. Accordingly, Applicant requests the expeditious allowance of the pending claims.

The undersigned has made a good faith effort to respond to all of the rejections in the case and to place the claims in condition for immediate allowance. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is respectfully requested to call the undersigned to discuss such issues.

**Appl. No.** : 10/068,447  
**Filed** : February 6, 2002

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,  
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